UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,420	07/23/2003	Nancy Auestad	6960USP1	9175

25755 7590 11/17/2006

ROSS PRODUCTS DIVISION OF ABBOTT LABORATORIES
DEPARTMENT 108140-DS/1
625 CLEVELAND AVENUE
COLUMBUS, OH 43215-1724

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/625,420	AUESTAD ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-11 are presented for examination.

Applicant's Amendment filed August 23, 2006 has been received and entered into the present application.

Claims 1-11 remain pending and are under examination. Claims 12-29 have been cancelled and claims 1, 4, 7 and 9 are amended.

Applicants' arguments, filed August 23, 2006, have been fully considered and are persuasive regarding previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. However, upon reconsideration of the claims presented by Applicant in the submission dated August 23, 2006, the following rejections are newly applied as a result of Applicant's amendments. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102 (New Grounds of Rejection)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bogentoft (WO 87/03198; 1987), in light of The Merck Index (Monograph 5383, page 867), Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; Abstract only) and Gil et al. (U.S. Patent 5,709,888; 1998), each cited to show a fact.

Bogentoft teaches a method for weight reduction by orally administering an effective weight reducing dosage of a hydrophobic substance in the form of an enteric preparation (page 5, second full paragraph) for the treatment of obesity (page 1, lines 1-3), wherein the hydrophobic substance is a fatty acid having 6-28 carbon atoms (page 3, second full paragraph), e.g., linolenic acid or linoleic acid (page 3, lines 8-11), wherein the one or more fatty acids is in the form of a triglyceride (page 6, first full paragraph), and is administered 2-5 hours before each meal, from 1-6 times per day (page 5, last full paragraph), and wherein the preparation may be used for an overweight subject (page 2, last full paragraph). Bogentoft additionally teaches the use of animal fats (i.e., "mixtures of esters of fatty acids of 6-28 carbon atoms and glycerol"; see paragraph bridging pages 3-4) in mixtures with the fatty acid(s).

The Merck Index is relied upon to show that linolenic acid is synonymous with alpha-linolenic acid. Please see Monograph 5383 at page 867. Brenna is cited to show that alpha-linolenic acid is an omega-3 fatty acid and that humans of all ages are capable of converting alpha-linolenic acid to the omega-3 long-chain polyunsaturated fatty acid docosahexaenoic acid. Please see the abstract.

In light of such facts, Bogentoft clearly anticipates the enteral administration of a long-chain n-3 polyunsaturated fatty acid (i.e., linolenic acid and/or docosaehexaenoic acid) in the form of a triglyceride to an overweight subject. Though docosahexaenoic acid is not explicitly taught by the reference, the art recognized such a fatty acid as a conversion product of alpha-linolenic acid and is, therefore, inherently present by the teaching of linolenic acid itself.

Additionally, Bogentoft clearly provides for embodiments where the fatty acid is administered as the sole active hydrophobic component of the composition, which meets Applicant's limitation of present claim 3, which is directed to administration of the long-chain n-3 polyunsaturated fatty acid independent of arachidonic acid.

Regarding the limitation of present claim 7, which requires the administration of both a long-chain n-3 and a long-chain n-6 polyunsaturated fatty acid in the form of a triacylglycerol, it is herein

noted that Bogentoft clearly teaches, and, thus, anticipates, embodiments wherein the hydrophobic substance comprises one or more fatty acids in the form of a triglyceride (see page 6, first full paragraph) and expressly names, for example, both linolenic acid (i.e., a long-chain n-3 polyunsaturated fatty acid, see *supra*) and linoleic acid (i.e., a long-chain n-6 polyunsaturated fatty acid, see Gil et al., col.1, lines 13-23, cited as evidence).

Regarding the administration "prior to or in conjunction with an appetite-impacting stimulus" (see present claims 4 and 9), it is herein reiterated that the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood. Accordingly, the teachings of Bogentoft properly anticipate the administration "prior to or in conjunction with an appetite-impacting stimulus", because growth of the human body would necessarily be present at any time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth. Although Applicant has remarked that an "appetite-impacting stimulus" has been defined as a stressor or stimuli that may increase food intake, such as irregular meal times, sleep deprivation and parenteral expectations to excel in school and/or sports (see page 8 of Applicant's remarks), it is noted that Applicant has only provided an exemplary list of such stressors and, therefore, given the definition that has been provided in the specification at page 18, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary.

Though Bogentoft teaches weight reduction and does not expressly teach a decrease in appetite of the subject to whom the hydrophobic substance is administered, the administration of the same compound (i.e., a long-chain n-3 polyunsaturated fatty acid) to the same host (i.e., an overweight subject) is considered to inherently have the claimed appetite reducing properties, whether expressly recognized by Bogentoft or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference

MPEP §2112.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the appetite reduction was not itself recognized as a pharmacological effect of administering the hydrophobic fatty acid composition to overweight or obese patients, such an effect is not considered a new therapeutic application because the known treatment of obesity or overweight status using this active agent(s) was already known in the prior art. Though mechanisms of action of chemical entities are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 is based upon the therapeutic applications and effects of the compounds, not the mechanism by which they exert such a therapeutic effect. Furthermore, it is generally well settled in the courts that a mechanistic or previously unappreciated property of a chemical compound, or combination of chemical compounds, when administered under identical conditions, is necessarily present, despite the fact that it may not have been readily apparent to, or recognized by, one of ordinary skill in the art.

Claim Rejections - 35 USC § 103 (New Grounds of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of

each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bogentoft (WO 87/03198; 1987), in light of The Merck Index (Monograph 5383, page 867 and Monograph 792, page 121), Brenna JT ("Efficiency of Conversion of [alpha]-Linolenic Acid to Long Chain n-3 Fatty Acids in Man", *Current Opinion in Clinical Nutrition and Metabolic Care*, 5(2):127-132, March 2002; Abstract only) and Gil et al. (U.S. Patent 5,709,888; 1998), each cited to show a fact.

Bogentoft teaches a method for weight reduction by orally administering an effective weight reducing dosage of a hydrophobic substance in the form of an enteric preparation (page 5, second full paragraph) for the treatment of obesity (page 1, lines 1-3), wherein the hydrophobic substance is a fatty acid having 6-28 carbon atoms (page 3, second full paragraph), e.g., linolenic acid or linoleic acid (page 3, lines 8-11), wherein the one or more fatty acids is in the form of a triglyceride (page 6, first full paragraph), and is administered 2-5 hours before each meal, from 1-6 times per day (page 5, last full paragraph), and wherein the preparation may be used for an overweight subject (page 2, last full paragraph). Bogentoft additionally teaches the use of animal fats (i.e., "mixtures of esters of fatty acids of 6-28 carbon atoms and glycerol"; see paragraph bridging pages 3-4) in mixtures with the fatty acid(s).

The Merck Index is relied upon to show that linolenic acid is synonymous with alpha-linolenic acid. Please see Monograph 5383 at page 867. Brenna is cited to show that alpha-linolenic acid is an omega-3 fatty acid and that humans of all ages are capable of converting alpha-linolenic acid to the omega-3 long-chain polyunsaturated fatty acid docosahexaenoic acid. Please see the abstract.

In light of such facts, Bogentoft clearly anticipates the enteral administration of a long-chain n-3 polyunsaturated fatty acid (i.e., linolenic acid and/or docosaehexaenoic acid) in the form of a triglyceride to an overweight subject. Though docosahexaenoic acid is not explicitly taught by the reference, the art

recognized such a fatty acid as a conversion product of alpha-linolenic acid and is, therefore, inherently present by the teaching of linolenic acid itself.

Additionally, Bogentoft clearly provides for embodiments where the fatty acid is administered as the sole active hydrophobic component of the composition, which meets Applicant's limitation of present claim 3, which is directed to administration of the long-chain n-3 polyunsaturated fatty acid independent of arachidonic acid.

Regarding the limitation of present claim 7, which requires the administration of both a long-chain n-3 and a long-chain n-6 polyunsaturated fatty acid in the form of a triacylglycerol, it is herein noted that Bogentoft clearly teaches, and, thus, anticipates, embodiments wherein the hydrophobic substance comprises one or more fatty acids in the form of a triglyceride (see page 6, first full paragraph) and expressly names, for example, both linolenic acid (i.e., a long-chain n-3 polyunsaturated fatty acid, see *supra*) and linoleic acid (i.e., a long-chain n-6 polyunsaturated fatty acid, see Gil et al., col.1, lines 13-23, cited as evidence).

Regarding the administration "prior to or in conjunction with an appetite-impacting stimulus" (see present claims 4 and 9), it is herein reiterated that the human body is a dynamic entity and is constantly in a state of growth and change, throughout infancy, adolescence or adulthood. Accordingly, the teachings of Bogentoft properly anticipate the administration "prior to or in conjunction with an appetite-impacting stimulus", because growth of the human body would necessarily be present at any time the composition was administered. Furthermore, growth periods are reasonably considered a period of stress on the human body and require proper nutrition and health in order to achieve such growth. Although Applicant has remarked that an "appetite-impacting stimulus" has been defined as a stressor or stimuli that may increase food intake, such as irregular meal times, sleep deprivation and parenteral expectations to excel in school and/or sports (see page 8 of Applicant's remarks), it is noted that Applicant has only provided an exemplary list of such stressors and, therefore, given the definition that

has been provided in the specification at page 18, periods of growth are reasonably considered to fall within the scope of such a term, absent factual evidence to the contrary.

Though Bogentoft teaches weight reduction and does not expressly teach a decrease in appetite of the subject to whom the hydrophobic substance is administered, the administration of the same compound (i.e., a long-chain n-3 polyunsaturated fatty acid) to the same host (i.e., an overweight subject) is considered to inherently have the claimed appetite reducing properties, whether expressly recognized by Bogentoft or not. Products of identical chemical composition cannot exert mutually exclusive properties when administered under the same circumstances or, in the present case, the same host. Please reference MPEP §2112.

The explanation of an effect obtained when using a compound cannot confer novelty on a known process if the skilled artisan was already aware of the occurrence of the desired therapeutic effect. In other words, even if the appetite reduction was not itself recognized as a pharmacological effect of administering the hydrophobic fatty acid composition to overweight or obese patients, such an effect is not considered a new therapeutic application because the known treatment of obesity or overweight status using this active agent(s) was already known in the prior art. Though mechanisms of action of chemical entities are no doubt important contributions to scientific and pharmaceutical development, the assessment of patentability under 35 U.S.C. 102 is based upon the therapeutic applications and effects of the compounds, not the mechanism by which they exert such a therapeutic effect. Furthermore, it is generally well settled in the courts that a mechanistic or previously unappreciated property of a chemical compound, or combination of chemical compounds, when administered under identical conditions, is necessarily present, despite the fact that it may not have been readily apparent to, or recognized by, one of ordinary skill in the art.

Regarding the administration of docosahexaenoic acid in combination with arachidonic acid, Bogentoft clearly contemplates embodiments wherein the hydrophobic substance comprises a mixture of

both a fat, such as an animal fat, in combination with a fatty acid component (see paragraph bridging pages 3-4). In light of the fact that Bogentoft specifically teaches the use of linolenic acid (i.e., a long-chain n-3 polyunsaturated fatty acid that is converted to docosahexaenoic acid in humans; see Brenna, discussed *supra*) as the active agent of the hydrophobic formulation and also combinations of fatty acids with fats, such as animal fats, each for the same therapeutic utility of treating obesity by reducing weight, one of ordinary skill in the art would have found it *prima facie* obvious to combine the linolenic acid (i.e., a source of docosahexaenoic acid) with a fat, such as animal fat, because the artisan would have reasonably expected additive, if not synergistic, weight reducing effects when combined. Additionally, The Merck Index is cited to show that arachidonic acid was known in the art as a major constituent of animal depot fats (see Monograph 792, page 121).

As stated in *In re Kerkhoven*, 626 F.2d 846, 205 USPQ 1069, at page 1072 (CCPA 1980): "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (CCPA 1960)."

Regarding the claimed dosage amounts of polyunsaturated fatty acid(s), the differences between the dosage amounts of the instant application and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because the determination of the optimum dosage amounts of the active fatty acid component(s) would have been a matter well within the purview of one of ordinary skill in the art. Such a determination would have been made in accordance with a variety of factors, such as the age, weight, sex, diet and medical condition of the patient, severity of the disease, the route of administration, pharmacological considerations, such as the activity, efficacy, pharmacokinetics and toxicology profiles of the particular compound employed, whether a drug delivery system is utilized and

whether the compound is administered as part of a drug combination. Thus, the concentrations that would have actually been employed would have varied widely and, in the absence of evidence to the contrary, the currently claimed specific dosage amounts are not seen to be inconsistent with those that would have been determined by the skilled artisan.

In addition, the concentration of the active ingredient(s) is a result-effective variable, i.e., a variable that achieves a recognized result, and, therefore, the determination of the optimum of workable dosage range would be well within the practice of routine experimentation by the skilled artisan, absent factual evidence to the contrary, and, further, absent any evidence demonstrating a patentable difference between the compositions used and the criticality of the amount(s).

Applicant's attention is further directed to the MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges in the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." Although the present claims are directed to milligram concentrations, such a motivation is nonetheless relevant.

Conclusion

Rejection of claims 1-11 is proper.

No claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the

mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie A. Royds
Patent Examiner
Art Unit 1614

November 12, 2006

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER